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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/719,295	11/21/2003	Carl Berger	163.1.004	3011
<div>7590 06/25/2007</div> <div>Allen R. Kipnes, Esq. WATOV & KIPNES, P.C. P.O. Box 247 Princeton Junction, NJ 08550</div> <div>EXAMINER SCHLIENTZ, NATHAN W</div> <div>ART UNIT 1616 PAPER NUMBER</div> <div>MAIL DATE 06/25/2007 DELIVERY MODE PAPER</div>				

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/719,295

Applicant(s)

BERGER, CARL

Examiner

Nathan W. Schlientz

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 March 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 5-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 5-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Claims

Claim 1 was amended by an Amendment filed 8 March 2007. Claims 1, 2 and 5-25 are pending and are examined herein on the merits for patentability. No claim is allowed at this time.

Response to Arguments

Applicant's arguments, see page 8, lines 20-22, filed 8 March 2007, with respect to the rejections of Claims 1, 2 and 5-25 under 35 U.S.C. 103(a) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, new grounds of rejection are made, as detailed below.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1,148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1. Claims 1, 2, 5-14 and 16-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,713,376 (hereinafter Berger '376) in view of Musser et al., Nature, 11 April 2002, 416, 599-600 (hereinafter Musser et al.).

Applicant claims:

Applicants claim a method of reducing the nicotine content of a tobacco plant through applying glucose oxidase to said plant in an amount effective inhibit the synthesis of nicotine such that upon use non-addictive levels in the CNS blood plasma of the user are achieved.

Applicants also claim a tobacco plant as well as tobacco plant leaves, which have been treated with glucose oxidase in an amount effective inhibit the synthesis of nicotine such that upon use non-addictive levels in the CNS blood plasma of the user are achieved, wherein the tobacco plant leaves are selected from *Nicotiana tabacum*, *Nicotiana rustica* and *Nicotiana glutinosa*.

Determination of the scope and content of the prior art

(MPEP 2141.01)

Berger '376 teach a desire to produce a tobacco product with decreased levels of nicotine to an extent that upon use non-addictive levels in the CNS blood plasma of the user are achieved (column 2, lines 35-38 and 51-59).

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

Berger '376 do not teach applying glucose oxidase to the tobacco plant. However, Musser et al. teach the saliva of the caterpillar *Helicoverpa zea* can reduce the amount of toxic nicotine released by the tobacco plant *Nicotiana tabacum* (page 599, first paragraph). Musser et al. further teach feeding by caterpillars with intact spinnerets, the principal secretory structures of the labial salivary glands of *Helicoverpa zea*, reduced foliar nicotine levels by over 26% compared with the control (page 599, middle column, lines 6-10). Musser et al. also teach treatment of individual leaves with one of four preparations: active purified glucose oxidase, unpurified salivary-gland extract, inactivated (autoclaved) purified glucose oxidase, or water, wherein leaves treated with salivary extract received 20 micrograms glucose oxidase in total (page 599, third column, lines 16-22). Musser et al. also teach each wound on the plant received 10 microliters of water (page 599, third column, lines 22-23), which according to the specification would be a suitable carrier (page 11, lines 21-22).

Finding of *prima facie* obviousness

Rational and Motivation (MPEP 2142-43)

Therefore, it would have been *prima facie* obvious for one skilled in the art at the time of the invention to reduce the amount of nicotine in *Nicotiana tabacum* to a non-addictive level, as taught by Berger '376, through applying glucose oxidase from *Helicoverpa zea*, or a biochemical source, as reasonably taught by Musser et al. The concentration of glucose oxidase or the necessary number of treatments to achieve

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non-addictive levels is well within the purview of a person skilled in the art at the time of the instant invention. A person skilled in the art would be motivated to determine the appropriate concentration or number of treatments of glucose oxidase required to achieve non-addictive levels in order produce a cigarette product that is non-addictive, as reasonably taught by Berger '376, which would inherently yield the tobacco plant and tobacco plant leaves containing non-addictive levels of nicotine.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

2. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Berger '376 and Musser et al., as applied to Claims 1, 2, 5-14 and 16-20 above, further in view of Hibi et al., The Plant Cell, 1994, 6, 723-735 (hereinafter Hibi et al.).

Applicant claims:

The Applicant claims a method of reducing the nicotine content of a tobacco plant through applying glucose oxidase to said plant in an amount effective inhibit the synthesis of nicotine such that upon use non-addictive levels in the CNS blood plasma of the user are achieved, wherein the tobacco plant is a genetically modified plant exhibiting reduced levels of nicotine as compared to non-genetically modified tobacco plants.

Determination of the scope and content of the prior art

(MPEP 2141.01)

Berger '376 teach a desire to produce a tobacco product with non-addictive levels of nicotine, as discussed above. Musser et al. teach glucose oxidase from *Helicoverpa zea* reduces nicotine levels in tobacco plants, as discussed above.

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

Neither Berger'376 nor Musser et al. teach reducing the level of nicotine in a genetically modified tobacco plant that exhibits reduced nicotine levels as compared to a non-genetically modified tobacco plant. However, genetic engineering of tobacco plants for the purpose of reducing nicotine levels is known in the art, and such methods have reduced nicotine in tobacco (specification, paragraph bridging pages 1 and 2). Also, Hibi et al. teach genetically modified tobacco plants (i.e. *nic1* and *nic2* mutations), which reduce levels of nicotine in said plants (abstract and page 733, 1st column, lines 8-10).

Finding of *prima facie* obviousness

Rational and Motivation (MPEP 2142-43)

Therefore, it would have been *prima facie* obvious for one skilled in the art at the time of the invention to apply glucose oxidase, as reasonably suggested by Musser et al., to genetically modified tobacco plants which already have reduced levels of nicotine, in order to obtain a tobacco product with non-addictive levels of nicotine. One of ordinary skill in the art would have been motivated to start with genetically modified

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tobacco plants which have reduced levels of nicotine as compared to non-genetically modified tobacco plants because the concentration or number of treatments of glucose oxidase would be less than required for non-genetically modified tobacco plants in order to achieve non-addictive levels of nicotine.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Contact Information


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nathan W. Schlientz whose telephone number is 571-272-9924. The examiner can normally be reached on 8:30 AM to 5:00 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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